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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/567,238	02/03/2006	Carlos Matute Almau	P/4043-258	2543

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EXAMINER	
CRUZ, KATHRIEN ANN	
ART UNIT	PAPER NUMBER
1628	
MAIL DATE	DELIVERY MODE
02/01/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/567,238	MATUTE ALMAU ET AL.	
	Examiner	Art Unit	
	KATHRIEN CRUZ	1628	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11/16/2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *3 and 4* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3-4* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 3-4 are pending.

Applicants response filed November 16, 2010 has been receive and entered in the application.

Priority

This application is a nation stage entry of PCT/ES04/00361 (dated 08/04/2004) which claims benefit of foreign priority P200301853 (dated 08/04/2003).

Action Summary

Claims 3 and 5 are rejected under 35 U.S.C. 112, second paragraph is withdrawn.

Claims 5-6 are rejected under 35 U.S.C. 102(b) as being anticipated is withdrawn due to applicants cancellation of claims,

Claims 3-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smith (The P2X7 purinergic receptor on bovine macrophages mediates mycobacterial death, Veterinary Immunology and Immunopathology, 78, 2001, pg 249-262) as applied to claims 5-6 above, and Neely (WO 99/38532) and in view of Jameson et al (U.S. Patent 5,589,458) all are of record and further in view of Steinman (Multiple Sclerosis: Deeper Understanding of Its Pathogenesis reveal New Targets for Therapy, 2002, Annu. Reb Neurosco. Vol. 25, pages 491-505) is maintained.

Response to Arguments

Applicants argue that the cited references does not contain any mention regarding the treatment of, specifically, the neurodegenerative phase of multiple sclerosis as recited in instant claims 3 and 4. This argument has been fully considered but has not been found persuasive. The instant claims 3-4 are drawn to a method of preparing a drug not a method of treatment, therefore the intended use of the drug is irrelivenent and not given patentability weight.

Applicants argue that the P2X7 act by protecting against toxicity induced by ATP during the neurodegenerative phase of Multiple Sclerosis. This argument has been fully considered but has not been found persuasive. The instant claims 3-4 are drawn to a method of preparing a drug not a method of treatment, therefore the intended use of the drug is irrelivenent and not given patentability weight. Furthermore, Neely teaches a method of inhibiting fibrosis and/or sclerosis in a subject afflicted with a fibrosing or sclerosing disorder by administering an amount of P2X purinoceptor antagoinist (page 4, lines 14-17). Neely teaches that sclerosis are muscular function loss cause by increase fibrosis (page 8, lines 19-20). Smith teaches that P2X7 is an ionotropic ATP gated channel that plays a role in a variety of immune response (page 249, introduction) and an important effector pathway in the immune response (page 260, first paragraph). Smith teaches that o-ATP and KN-62 are P2X7 purinergic receptor antagonist (page 260, first paragraph). It would have been obvious to one of ordinary skills in the art that administering an P2X7 purinergic receptor antagonist would inhibit fibrosis and/or sclerosis in a subject suffering from a fibrosing or sclerosin disorder (e.g. multiple

sclerosis) as taught by Neely and since it is known in the art that that o-ATP and KN-62 are P2X7 purinergic receptor antagonist as taught by Smith, it is obvious that the administration of that o-ATP and KN-62 are P2X7 purinergic receptor antagonist would also treat multiple sclerosis. Therefore, the rejection under 35 U.S.C. 103(a) is deemed proper.

For the ease of the applicant the previous office action dated August 25, 2010 is reproduced below.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 3-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smith (The P2X7 purinergic receptor on bovine macrophages mediates mycobacterial

death, Veterinary Immunology and Immunopathology, 78, 2001, pg 249-262) as applied to claims 5-6 above, and Neely (WO 99/38532) and in view of Jameson et al (U.S. Patent 5,589,458) all are of record and further in view of Steinman (Multiple Sclerosis: Deeper Understanding of Its Pathogenesis reveal New Targets for Therapy, 2002, Annu. Reb Neurosco. Vol. 25, pages 491-505).

Smith teaches that P2X7 is an ionotropic ATP gated channel that plays a role in a variety of immune response (page 249, introduction) and an important effector pathway in the immune response (page 260, first paragraph). Smith teaches that o-ATP and KN-62 are P2X7 purinergic receptor antagonist (page 260, first paragraph).

Smith does not expressly teach the treatment of neurodegenerative phase of multiple sclerosis.

Neely teaches a method of inhibiting fibrosis and/or sclerosis in a subject afflicted with a fibrosing or sclerosing disorder by administering an amount of P2X purinoceptor antagoinist (page 4, lines 14-17). Neely teaches that sclerosis are muscular function loss cause by increase fibrosis (page 8, lines 19-20).

Jameson teaches that autoimmune diseases are characterized as an immune reaction against "self" antigens. Autoimmune diseases include systemic lupus erythematosus (SLE), rheumatoid arthritis (RA) and **multiple sclerosis (MS)** (column 1, lines 22-25).

Steinman teaches that multiple sclerosis (MS) often begins in early adulthood with an autoimmune inflammatory strike against components of the myelin sheath. Paralysis, sensory disturbances, in coordination, and visual impairment are common

features. The disease often starts with an attack lasting for days to weeks, followed by remission lasting months to years. This relapsing remitting phase often last for five to ten years. About 30% of individuals with relapsing-remitting MS enter into a secondary chronic progressive state. This chronic progressive state is often characterized by the inability to walk, which leaves the MS patient wheelchair-bound. In the chronic progressive phase, distinct attacks are rare, and the disease progresses insidiously. In rare instances, clinical disability begins with this progressive phase and in this case the disease is called primary progressive MS (page 491, second paragraph bridging page 492 first paragraph). Steinman teaches that the use of neuroprotective agents that block sub-types of glutamate receptors has been a prime direction in the development of new therapies for neurodegenerative conditions and may prove useful for the chronic degenerative phase of MS. Steinman teaches that recognition of an inflammatory and a neurodegenerative phase of MS has allowed the targeting of therapies specific for varies phase of MS (page 502, second paragraph).

It would have been obvious to one or ordinary skills in the art at the time of the invention to treat an autoimmune disease such as the neurodegenerative phase of multiple sclerosis. One would have been motivated to treat of autoimmune disease such as the neurodegenerative phase of multiple sclerosis because o-ATP is an important effector pathway in the immune response as taught by Smith and P2X purinoceptor antagonist are useful in the treatment of fibrosis and/or sclerosis as taught by Neely. Additionally, it is known in the art that by recognizing an inflammatory and a neurodegenerative phase of MS has allowed the targeting of therapies specific for

varies phase of multiple sclerosis which is also an autoimmune disease as taught by both Jameson and Steinman.

For these reasons, the claimed subject matter is deemed to fail to be patentably distinguishable over the state of the art as represented by the cited reference. The claims are therefore, properly rejected under 35 U.S.C. 103.In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.

Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Conclusion

Claims 3-4 are rejected.

No claims are allowed.

Communication

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KATHRIEN CRUZ whose telephone number is (571)270-5238. The examiner can normally be reached on Mon - Thurs 7:00am - 5:00pm with every Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brandon Fetterolf can be reached on (571) 272-2919. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/KATHRIEN CRUZ/
Examiner, Art Unit 1628

/San-ming Hui/
Primary Examiner, Art Unit 1628